



PTO/SB/08a/b (07-06)

Approved for use through 09/30/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known			
				Application Number		10/758,335-Conf. #6410	
				Filing Date		January 15, 2004	
				First Named Inventor		Seth J. ORLOW	
				Art Unit		1614	
				Examiner Name			
				J. D. Anderson			
Sheet	1	of	2	Attorney Docket Number			
0071369.00368US1							

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
JDA	AA*	US-5,628,987	05-13-1997	Fuller	
JDA	AB	US-5,686,103	11-11-1997	Redziniak et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ³
		Country Code ⁴ -Number ⁵ -Kind Code ⁶ (if known)				
JDA	BA	WO-97/00892	01-09-1997	The Government of the United States of America, represented by The Secretary Department of Health and Human Services		
JDA	BB	WO-01/01131	01-04-2001	Univ New York		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with a single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.88(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 801.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.					T ²
JDA	CA	ABDEL-MALEK, et al., "Mitogenic, Melanogenic and cAMP Responses of Cultured Neonatal Human Melanocytes to Commonly Used Mitogens", Journal of Cellular Physiology, 150:416-425 (1992)					
JDA	CB	ANCANS, et al., "Activation of Melanogenesis by Vacuolar Type H ⁺ -ATPase Inhibitors in Amelanotic, Tyrosinase Positive Human and Mouse Melanoma Cells", FEBS Letters, 478:57-60 (2000)					
JDA	CC	ANSEL, et al., Pharmaceutical Dosage Forms and Drug Delivery Systems, Sixth Ed., A Lea & Febiger Book, Williams & Wilkins, Baltimore (1995) (cover of book and page (i))					
JDA	CD	BOUCHARD, et al., "Induction of Pigmentation in Mouse Fibroblasts by Expression of Human Tyrosinase cDNA", J. Exp. Med., 169:2029-2042 (1989)					
JDA	CE	BRILLIANT, et al., "Anatomy of Pigment Cell Genes Acting at the Cellular Lever", in <u>The Pigmentary System: Physiology and Pathophysiology</u> , Norlund, et al., eds., Oxford University Press, Chapter 18, pp. 217-229 (1998)					
JDA	CF	CHAKRABORTY, et al., "Effect of Arbutin on Melanogenic Proteins in Human Melanocytes", Pigment Cell Research, 11:206-212 (1998)					
JDA	CG	GARDNER, et al., "The Complete Nucleotide Sequence of an Infectious Clone of Cauliflower Mosaic Virus by M13mp7 Shotgun Sequencing", Nucleic Acids Research, 9(12):2871-2888 (1981)					
JDA	CH	GILBERT, et al., "Useful Proteins from Recombinant Bacteria", Sci. Am., 242(4):74-94 (1980)					
JDA	CI	HARLOW, et al., <u>Antibodies – A Laboratory Manual</u> , Cold Spring Harbor Laboratory (1988) (cover of book and page (i))					
JDA	CJ	HU, et al., "Regulation of Melanogenesis by Human Uveal Melanocytes In Vitro", Exp. Eye					

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known																																																																																																																																																																	
				Application Number	10/758,335-Conf. #6410																																																																																																																																																																
				Filing Date	January 15, 2004																																																																																																																																																																
				First Named Inventor	Seth J. ORLOW																																																																																																																																																																
				Art Unit	1614																																																																																																																																																																
				Examiner Name	J. D. Anderson																																																																																																																																																																
Sheet	2	of	2	Attorney Docket Number	0071369.00368US1																																																																																																																																																																
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="2"></td> <td colspan="4">Res., 64:397-404 (1997)</td> </tr> <tr> <td colspan="2">JDA</td> <td>CK</td> <td colspan="4">IMOKAWA, et al., "Skin Organ Culture Model for Examining Epidermal Melanization", Journal of Investigative Dermatology, 100:47-54 (1993)</td> </tr> <tr> <td colspan="2"></td> <td>CL</td> <td colspan="4">JIMENEZ, et al., "Tyrosinases from Two Different Loci are Expressed by Normal and by Transformed Melanocytes", Journal of Biological Chemistry, 266(2):1147-1156 (1991)</td> </tr> <tr> <td colspan="2"></td> <td>CM</td> <td colspan="4">KUZUMAKI, et al., "Eumelanin Biosynthesis is Regulated by Coordinate Expression of Tyrosinase and Tyrosinase-Related Protein-1 Genes", Experimental Cell Research, 207:33-40 (1993)</td> </tr> <tr> <td colspan="2"></td> <td>CN</td> <td colspan="4">LERNER, et al., "Biochemistry of Melanin Formation", Physiol. Rev., 30(1):91-126 (1950)</td> </tr> <tr> <td colspan="2"></td> <td>CO</td> <td colspan="4">MACDONALD, "Expression of the Pancreatic Elastase I Gene in Transgenic Mice", Hepatology, 7(1):42S-51S (1987)</td> </tr> <tr> <td colspan="2"></td> <td>CP</td> <td colspan="4">MASON, et al., "The Hypogonadal Mouse: Reproductive Functions Restored by Gene Therapy", Science, 234(4782):1372-1378 (1986)</td> </tr> <tr> <td colspan="2"></td> <td>CQ</td> <td colspan="4">NIEKRASZ, et al., "The Pig as Organ Donor for Man", Transplantation Proceedings, 24(2):625-626 (1992)</td> </tr> <tr> <td colspan="2"></td> <td>CR</td> <td colspan="4">OETTING, et al., "Mutations of the Human P Gene Associated with Type II Oculocutaneous Albinism (OCA2)", Human Mutation, 12(6):433-434 (1998) (abstract only)</td> </tr> <tr> <td colspan="2"></td> <td>CS</td> <td colspan="4">ORLOW, et al., "Retinoic Acid is a Potent Inhibitor of Inducible Pigmentation in Murine and Hamster Melanoma Cell Lines", Journal of Investigative Dermatology, 64(4):461-464 (1990)</td> </tr> <tr> <td colspan="2"></td> <td>CT</td> <td colspan="4">ORLOW, "The Biogenesis of Melanosomes", in <u>The Pigmentary System: Physiology and Pathophysiology</u>, Norlund, et al., eds, Oxford University Press, Chapter 6, pp. 97-106 (1998)</td> </tr> <tr> <td colspan="2"></td> <td>CU</td> <td colspan="4">ORNITZ, et al., "Elastase I Promoter Directs Expression of Human Growth Hormone and SV40 T Antigen Genes to Pancreatic Acinar Cells in Transgenic Mice", Cold Spring Harb. Symp. Quant. Biol., 50:399-409 (1985)</td> </tr> <tr> <td colspan="2"></td> <td>CV</td> <td colspan="4">PINKERT, et al., "An Albumin Enhancer Located 10 kb Upstream Functions Along with its Promoter to Direct Efficient, Liver-Specific Expression in Transgenic Mice", Genes & Development, 1:268-276 (1987)</td> </tr> <tr> <td colspan="2"></td> <td>CW</td> <td colspan="4">Product Information Sigma: Composition of the Medium MCDB-153</td> </tr> <tr> <td colspan="2"></td> <td>CX</td> <td colspan="4">Product Information Sigma: Composition of the Medium Ham's F10</td> </tr> <tr> <td colspan="2"></td> <td>CY</td> <td colspan="4">Remington's Pharmaceutical Sciences, 18th Edition, Alfonso Gennaro, Editor, Mack Publishing Company, Easton, PA (1990)</td> </tr> <tr> <td colspan="2"></td> <td>CZ</td> <td colspan="4">SAKAI, et al., "Modulation of Murine Melanocyte Function <i>in vitro</i> by Agouti Signal Protein", EMBO Journal, 16(12):3544-3552 (1997)</td> </tr> <tr> <td colspan="2"></td> <td>CA1</td> <td colspan="4">SCHWARTZ, et al., <u>Surface Active Agents, Their Chemistry and Technology</u>, Interscience Publishers, Inc, New York, NY (1949)</td> </tr> <tr> <td colspan="2"></td> <td>CB1</td> <td colspan="4">SEIBERG, et al., "Inhibition of Melanosome Transfer Results in Skin Lightening", J. Invest. Dermatol., 115:162-167 (2000)</td> </tr> <tr> <td colspan="2"></td> <td>CC1</td> <td colspan="4">SEIJI, et al., "Subcellular Localization of Melanin Biosynthesis", Annals NY Acad. Sci., 100:497-533 (1963)</td> </tr> <tr> <td colspan="2"></td> <td>CD1</td> <td colspan="4">SHANI, "Tissue-Specific Expression of Rat Myosin Light-Chain 2 Gene in Transgenic Mice", Nature, 314:283-286 (1985)</td> </tr> <tr> <td colspan="2">V</td> <td>CE1</td> <td colspan="4">VIRADOR, et al., "A Standardized Protocol for Assessing Regulators of Pigmentation", Analytical Biochemistry, 270:207-219 (1999)</td> </tr> <tr> <td colspan="2">JDA</td> <td>CF1</td> <td colspan="4">YOKOYAMA, et al., "Conserved Cysteine to Serine Mutation in Tyrosinase is Responsible for the Classical Albino Mutation in Laboratory Mice", Nucleic Acids Research, 18(24):7293-7298 (1990)</td> </tr> </table>								Res., 64:397-404 (1997)				JDA		CK	IMOKAWA, et al., "Skin Organ Culture Model for Examining Epidermal Melanization", Journal of Investigative Dermatology, 100:47-54 (1993)						CL	JIMENEZ, et al., "Tyrosinases from Two Different Loci are Expressed by Normal and by Transformed Melanocytes", Journal of Biological Chemistry, 266(2):1147-1156 (1991)						CM	KUZUMAKI, et al., "Eumelanin Biosynthesis is Regulated by Coordinate Expression of Tyrosinase and Tyrosinase-Related Protein-1 Genes", Experimental Cell Research, 207:33-40 (1993)						CN	LERNER, et al., "Biochemistry of Melanin Formation", Physiol. Rev., 30(1):91-126 (1950)						CO	MACDONALD, "Expression of the Pancreatic Elastase I Gene in Transgenic Mice", Hepatology, 7(1):42S-51S (1987)						CP	MASON, et al., "The Hypogonadal Mouse: Reproductive Functions Restored by Gene Therapy", Science, 234(4782):1372-1378 (1986)						CQ	NIEKRASZ, et al., "The Pig as Organ Donor for Man", Transplantation Proceedings, 24(2):625-626 (1992)						CR	OETTING, et al., "Mutations of the Human P Gene Associated with Type II Oculocutaneous Albinism (OCA2)", Human Mutation, 12(6):433-434 (1998) (abstract only)						CS	ORLOW, et al., "Retinoic Acid is a Potent Inhibitor of Inducible Pigmentation in Murine and Hamster Melanoma Cell Lines", Journal of Investigative Dermatology, 64(4):461-464 (1990)						CT	ORLOW, "The Biogenesis of Melanosomes", in <u>The Pigmentary System: Physiology and Pathophysiology</u> , Norlund, et al., eds, Oxford University Press, Chapter 6, pp. 97-106 (1998)						CU	ORNITZ, et al., "Elastase I Promoter Directs Expression of Human Growth Hormone and SV40 T Antigen Genes to Pancreatic Acinar Cells in Transgenic Mice", Cold Spring Harb. Symp. Quant. Biol., 50:399-409 (1985)						CV	PINKERT, et al., "An Albumin Enhancer Located 10 kb Upstream Functions Along with its Promoter to Direct Efficient, Liver-Specific Expression in Transgenic Mice", Genes & Development, 1:268-276 (1987)						CW	Product Information Sigma: Composition of the Medium MCDB-153						CX	Product Information Sigma: Composition of the Medium Ham's F10						CY	Remington's Pharmaceutical Sciences, 18th Edition, Alfonso Gennaro, Editor, Mack Publishing Company, Easton, PA (1990)						CZ	SAKAI, et al., "Modulation of Murine Melanocyte Function <i>in vitro</i> by Agouti Signal Protein", EMBO Journal, 16(12):3544-3552 (1997)						CA1	SCHWARTZ, et al., <u>Surface Active Agents, Their Chemistry and Technology</u> , Interscience Publishers, Inc, New York, NY (1949)						CB1	SEIBERG, et al., "Inhibition of Melanosome Transfer Results in Skin Lightening", J. Invest. Dermatol., 115:162-167 (2000)						CC1	SEIJI, et al., "Subcellular Localization of Melanin Biosynthesis", Annals NY Acad. Sci., 100:497-533 (1963)						CD1	SHANI, "Tissue-Specific Expression of Rat Myosin Light-Chain 2 Gene in Transgenic Mice", Nature, 314:283-286 (1985)				V		CE1	VIRADOR, et al., "A Standardized Protocol for Assessing Regulators of Pigmentation", Analytical Biochemistry, 270:207-219 (1999)				JDA		CF1	YOKOYAMA, et al., "Conserved Cysteine to Serine Mutation in Tyrosinase is Responsible for the Classical Albino Mutation in Laboratory Mice", Nucleic Acids Research, 18(24):7293-7298 (1990)			
		Res., 64:397-404 (1997)																																																																																																																																																																			
JDA		CK	IMOKAWA, et al., "Skin Organ Culture Model for Examining Epidermal Melanization", Journal of Investigative Dermatology, 100:47-54 (1993)																																																																																																																																																																		
		CL	JIMENEZ, et al., "Tyrosinases from Two Different Loci are Expressed by Normal and by Transformed Melanocytes", Journal of Biological Chemistry, 266(2):1147-1156 (1991)																																																																																																																																																																		
		CM	KUZUMAKI, et al., "Eumelanin Biosynthesis is Regulated by Coordinate Expression of Tyrosinase and Tyrosinase-Related Protein-1 Genes", Experimental Cell Research, 207:33-40 (1993)																																																																																																																																																																		
		CN	LERNER, et al., "Biochemistry of Melanin Formation", Physiol. Rev., 30(1):91-126 (1950)																																																																																																																																																																		
		CO	MACDONALD, "Expression of the Pancreatic Elastase I Gene in Transgenic Mice", Hepatology, 7(1):42S-51S (1987)																																																																																																																																																																		
		CP	MASON, et al., "The Hypogonadal Mouse: Reproductive Functions Restored by Gene Therapy", Science, 234(4782):1372-1378 (1986)																																																																																																																																																																		
		CQ	NIEKRASZ, et al., "The Pig as Organ Donor for Man", Transplantation Proceedings, 24(2):625-626 (1992)																																																																																																																																																																		
		CR	OETTING, et al., "Mutations of the Human P Gene Associated with Type II Oculocutaneous Albinism (OCA2)", Human Mutation, 12(6):433-434 (1998) (abstract only)																																																																																																																																																																		
		CS	ORLOW, et al., "Retinoic Acid is a Potent Inhibitor of Inducible Pigmentation in Murine and Hamster Melanoma Cell Lines", Journal of Investigative Dermatology, 64(4):461-464 (1990)																																																																																																																																																																		
		CT	ORLOW, "The Biogenesis of Melanosomes", in <u>The Pigmentary System: Physiology and Pathophysiology</u> , Norlund, et al., eds, Oxford University Press, Chapter 6, pp. 97-106 (1998)																																																																																																																																																																		
		CU	ORNITZ, et al., "Elastase I Promoter Directs Expression of Human Growth Hormone and SV40 T Antigen Genes to Pancreatic Acinar Cells in Transgenic Mice", Cold Spring Harb. Symp. Quant. Biol., 50:399-409 (1985)																																																																																																																																																																		
		CV	PINKERT, et al., "An Albumin Enhancer Located 10 kb Upstream Functions Along with its Promoter to Direct Efficient, Liver-Specific Expression in Transgenic Mice", Genes & Development, 1:268-276 (1987)																																																																																																																																																																		
		CW	Product Information Sigma: Composition of the Medium MCDB-153																																																																																																																																																																		
		CX	Product Information Sigma: Composition of the Medium Ham's F10																																																																																																																																																																		
		CY	Remington's Pharmaceutical Sciences, 18th Edition, Alfonso Gennaro, Editor, Mack Publishing Company, Easton, PA (1990)																																																																																																																																																																		
		CZ	SAKAI, et al., "Modulation of Murine Melanocyte Function <i>in vitro</i> by Agouti Signal Protein", EMBO Journal, 16(12):3544-3552 (1997)																																																																																																																																																																		
		CA1	SCHWARTZ, et al., <u>Surface Active Agents, Their Chemistry and Technology</u> , Interscience Publishers, Inc, New York, NY (1949)																																																																																																																																																																		
		CB1	SEIBERG, et al., "Inhibition of Melanosome Transfer Results in Skin Lightening", J. Invest. Dermatol., 115:162-167 (2000)																																																																																																																																																																		
		CC1	SEIJI, et al., "Subcellular Localization of Melanin Biosynthesis", Annals NY Acad. Sci., 100:497-533 (1963)																																																																																																																																																																		
		CD1	SHANI, "Tissue-Specific Expression of Rat Myosin Light-Chain 2 Gene in Transgenic Mice", Nature, 314:283-286 (1985)																																																																																																																																																																		
V		CE1	VIRADOR, et al., "A Standardized Protocol for Assessing Regulators of Pigmentation", Analytical Biochemistry, 270:207-219 (1999)																																																																																																																																																																		
JDA		CF1	YOKOYAMA, et al., "Conserved Cysteine to Serine Mutation in Tyrosinase is Responsible for the Classical Albino Mutation in Laboratory Mice", Nucleic Acids Research, 18(24):7293-7298 (1990)																																																																																																																																																																		
<small>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</small>																																																																																																																																																																					
<small>'Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.</small>																																																																																																																																																																					



PTO/SB/08A/B (09-06)

Approved for use through 03/31/2007. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				<i>Complete if Known</i>	
				Application Number	10/758,335-Conf. #6410
				Filing Date	January 15, 2004
				First Named Inventor	Seth J. ORLOW
				Art Unit	1614
				Examiner Name	J. D. Anderson
Sheet	1	of	1	Attorney Docket Number	0071369.00368US1/PFI-016CIPDV

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)			
					T ⁶

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 801.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

NON-PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
JDA	CA	HALL, et al., "Accumulation of Tyrosinase in the Endolysosomal Compartment in Induced by U18666A", Pigment Cell Res., 16:149-158 (2003)			
JDA	CB	KIM, et al., "Expression of a Thioredoxin-Related Protein-1 is Induced by Prostaglandin E2", Int. J. Cancer, 118:1670-1679 (2006)			
JDA	CC	MCCURDY, "Enzyme Localization During Melanogenesis", The Journal of Cell Biology, 43:220-228 (1969)			

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/James Anderson/	Date Considered	01/08/2007
--------------------	------------------	-----------------	------------